

REMARKS

The Final Office Action of June 4, 2007 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1- 37 are pending. Claims 1-6, 12-13, 17, 20, 22-31 and 33-36 were rejected under 35 U.S.C. § 102(3) as being anticipated by U.S. Patent Pub. No. 2001/0034542 to Mann (Mann). Claims 7-11 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann. Claims 14-16 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann in view of U.S. Patent Pub. No. 2004/0015205 to Whitehurst *et al.* (Whitehurst). Claims 18-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mann in view U.S. Patent No. 6,594,524 to Esteller *et al.* (Esteller).

In response, Applicants respectfully traverse the rejection with the following remarks.

Rejection of the Claims

Claims 1-6, 12-13, 17, 20, 22-31 and 33-36 were rejected under 35 U.S.C § 102(e) as being anticipated by Mann. The remaining claims were rejected under 35 U.S.C. § 103(a) in view of Mann, either alone or in combination with Whitehurst or Esteller. Claims 1 and 25 are independent.

Claim 1 is directed toward a method that includes the step of "assessing whether the first set of information is within a range of safety." The Office Action suggested that Mann disclosed this, pointing to pg. 2, paragraphs 11-12 of Mann. In particular, the Office Action suggests:

However, Mann discloses on page 2, paragraph 12, "a known threshold level, e.g., a known perception threshold level, a known comfortable threshold level, and/or a known maximum tolerable threshold level, for at least a plurality of the multiplicity of electrode contacts". The comfortable threshold level is considered to be the "safety" or "safe" information. If the stimulation is not comfortable, then it is not safe

Office Action, pg. 2. Applicants respectfully submit however, that it is incorrect to equate comfort with safety. Notably, the Office Action has provided no support for such a proposition. Applicants are unaware of any support for the proposition that something that is comfortable is

safe. Indeed, Applicants respectfully submit that many types of treatment are tolerable to a patient but would be considered unsafe.

In addition to the lack of support for the general proposition that comfort equates to safety, here such a suggestion has no basis. For example, as discussed on pg 35-37 of the specification as filed, charge density is based on the shape and configuration of the electrode as well as the stimulation applied. This is distinct from the concept of comfort. Thus, a comfortable stimulation for the patient in a first electrode might be safe while a similar stimulation in a second electrode (which would still feel comfortable) might be unsafe. Consequentially, a stimulation level that the patient would perceive as being with a tolerable range (e.g. comfortable) might be unsafe, depending on how it was applied.

Furthermore, as noted on page 35 of the specification as filed, treatment parameters could include a number of variables such as stimulation time, pulse shape, etc. Therefore, additional safety issues such as charge balancing, see specification as filed pg 36-37, and the like could arise, making what was otherwise a comfortable treatment unsafe.

The basis for the Office Action's rejection of the claims is that comfort can be equated with safety. However, for at least the reasons discussed above, it is incorrect to equate something being comfortable with something being safe. Therefore, the Office Action has failed to provided support that Mann discloses verifying whether something is safe.

Claim 1 further recites the feature of "if the first treatment therapy is not safe, executing a corrective action." Applicants submit that the Office Action did not provide any support for Mann disclosing this feature of claim 1. In this regard, Applicants note that rejection appears to rely on the incorrect suggestion that comfort is the same as safety. However, as noted above, an otherwise comfortable stimulation might not be safe. In other words, Mann could increase stimulation to a level that was comfortable (e.g. provided an acceptable level of treatment for a particular symptom) while at the same time providing a stimulation that was unsafe.

Therefore, for at least the above reasons Mann fails to disclose all the features of claim 1. As Mann fails to disclose all the features of claim 1, Mann cannot be said to anticipate claim 1. Therefore, claim 1 is patentable in view of Mann.

Claims 2-24 and 34-37 depend from claim 1 and the basis for the rejection is that Mann discloses all the features of claim 1. However, as noted above, Mann fails to disclose all the features of claim 1 because comfort and safety are distinct concepts that cannot be properly equated. Therefore, claims 2-24 and 34-37 are patentable for at least the reasons that claim 1 is and for the additional features recited therein.

In addition the underlying patentability of claim 1, claims 7-11 and 21 have an additional basis for being patentable. The Office Action admits that Mann fails to disclose the feature of claims 7-11 and 21 but suggests that claims 7-11 and 21 are obvious in view of Mann anyway because, while Mann fails to disclose the recited features, there is allegedly no disclosure regarding the advantages of such an approach. While not agreeing with this suggestion, one advantage of receiving labels from the user, as recited in claim 7, for example, is that it can help simplify the selection of treatment options, which would otherwise be so numerous as to make selection difficult. Furthermore, claim 8 recites the step of “comparing the first set of information and the other set of information.” One advantage this provides is the ability to compare different treatment therapy configurations before saving them. Given the limited memory for storing information and the potential confusion of having two treatments that are essentially the same, such a step allows for subsequent steps such as saving the information or providing a notification to the user, depending on whether the information is essentially unique. The admitted failure of Mann to disclose such steps makes it plain that the system of Mann would be unable to provide such benefits and therefore would not perform as well. Therefore, in view of the above provided advantages and the admitted failure of Mann to disclose such features, claims 7-11 and 21 are patentable over Mann for these additional reasons.

In addition to the above noted deficiency of Mann as it relates to claim 1, claim 14 recites the feature of “determining a surface area of the electrode” and the feature of “determining a charge density that is associated with the electrode.” The Office Action admits that Mann fails to disclose these feature and points to Whitehurst, pg. 3, ¶ 46 as correcting this deficiency. However, this section of Whitehurst makes no mention of “determining a surface area of the electrode.” Instead, Whitehurst merely indicates that applying a greater current requires more electrode surface area:

also requires electrodes with a relatively large surface area, so as to maintain safe levels of charge density and current density.

Whitehurst, pg. 3, ¶ 46. Plainly, the mere suggestion that larger currents require more surface area falls far short of disclosing the step of “determining a surface area of the electrode” recited in claim 14. For example, Whitehurst does not disclose any type of determining with respect to surface area of electrodes. The cited portion of Whitehurst also completely fails to disclose determining a charge density. Thus, the Office Action has failed to provide any support for these features being present in the references of record. Claims 15-16 depend from claim 14 also recite additional features related to the determining of charge density and the cited references make no mention of such steps. Accordingly, for at least this additional reason claims 14-16 are patentable over the references of record.

Independent claim 25 recites features similar to the features discussed above with respect to claim 1. Therefore, for claim 25 is patentable in view of Mann for reasons similar to the reasons discussed above with respect to claim 1.

Claims 26-33 depend from claim 25 and are patentable for at least the reasons that claim 25 is patentable and for the additional features recited therein. In particular, claim 32 recites features similar to the above recited features of claim 14 and therefore is patentable in view of the references of record for at least the reasons that claim 14 is patentable.

Accordingly, withdrawal of these grounds of rejection is respectfully requested.

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CONCLUSION

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and earnestly solicits prompt notification of the same.

Respectfully submitted,

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